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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,367	12/22/2003	Mahendra R. Patel	4-33515P1	7967
1095	7590	10/19/2007		
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			EXAMINER KENNEDY, SHARON E	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 10/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/743,367

Applicant(s)

PATEL ET AL.

Examiner

Sharon E. Kennedy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to: See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 07/26/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussain et al., US 7,037,523. Hussain discloses a controlled release composition for antibiotic drugs such as clarithromycin (column 5, line 33) in an amount from 30 to 75 wt. % (column 5, line 34) in combination with insoluble polymers such as ethyl cellulose having a viscosity grade of 20 cps (column 5, lines 39-56). The insoluble polymers are present in an amount from 10 to about 40 weight percent (column 5, line 60). Hussain fails to disclose a polymer component being present in an amount greater than 50 weight percent. However, the examiner takes the position that in view the ranges are close (the Hussain 40 wt % as opposed to the claimed greater than 50 wt

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%), it would be obvious to one of ordinary skill in the art to slightly modify the ingredients of the Hussain to include more than 50 wt % of polymer dependent upon the drug used, its activity level, and the patient need. Regarding claim 2, Hussain prefers ethyl cellulose (column 5, lines 39-47), however, it would be *prima facie* obvious to one of ordinary skill in the art to choose methyl cellulose in view of the close structural similarity in the lack of a showing of criticality. See MPEP 2144.09 for the case law concerning *prima facie* obviousness rejections using this rationale. Regarding claim 6, see column 5, line 13, disclosure of clarithromycin. See column 5, lines 33-38 for the drug weight percentage ranges.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussain as applied to claims 1-2 above, and further in view of Al-Razzak et al., US 6,010,718. Al Razzak exemplifies that the use of low viscosity hydroxypropylmethyl cellulose (Methocel), etc., is well known in the art for providing sustained release tablet formulations for antibiotics such as clarithromycin (Table 1). It would be obvious to one of ordinary skill in the art to substitute the ethyl cellulose for the Methocel in view that the identical antibiotics are delivered, indicating a high probability of success.

### ***Response to Arguments***

Applicant's arguments filed 07/26/2007 have been fully considered but they are not persuasive. Applicant's arguments seem centered on whether Hussain discloses water insoluble polymers, however, nothing in applicant's claims require the polymers to be water soluble. All applicant requires is a viscosity less than about 50 cps and that the polymer be hydrophilic.

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***Conclusion***

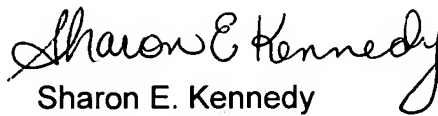
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

  
Sharon E. Kennedy  
Primary Examiner  
Art Unit 1615